

Docket No.: 085523-0381114
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF	:		
Philip THONHAUSER et al.	:	EXAMINER:	Duy Vu N. DEO
SERIAL NO.: 10/578,593	:	ART GROUP NO.:	1792
FILED: May 8, 2006	:	CONFIRMATION NO.:	1729
FOR: CLEANING	:		
DISINFECTION AND	:		
INDICATOR AGENT	:		

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1. I, Christian Thonhauser, am a co-inventor of U.S. Patent Application No. 10/578,593 ("the '593 application"). The '593 application is published as U.S. Pub. No. 20070102665 ("the '665 publication").
2. The non-final Office Action of February 18, 2010, rejected Claims 1-5 and 19, 20 as pending in the Amendment of September 8, 2009, under 35 U.S.C. § 103(a) as allegedly being obvious over AT408987B (referred to as AT) in view of RU2191163C1 (referred to as RU). Claims 9-11, 13-15, 18, 22-29 were rejected as allegedly being obvious over AT in view of RU, further in view of admitted prior art. Claims 6, 7 and 21 were rejected as allegedly being obvious over AT in view of RU, further in view of Wegner (US 2003/0151024).
3. On March 3, 2010, I interviewed the Examiner along with my counsel, Dr. Raj S. Davé. During the interview, I suggested providing unexpected result over a

composition according to the combination of the AT and RU references to overcome the obviousness rejections under AT/RU. The Examiner stated he would not be able to speculate on the unexpected results since it had not yet been submitted, but the unexpected results would be considered once filed.

4. On August 18, 2010, a response to the Office Action of February 18, 2010, was filed without a declaration showing unexpected results, as I needed some additional time to submit the laboratory results showing unexpected results.
5. On November 2, 2010, the Examiner mailed the final Office Action, continuing to reject Claims 1-7 and 19, 20 as pending in the Amendment of August 18, 2010, as allegedly being obvious over AT in view of RU. Claims 9-11, 13-15, 18, 22-29 were rejected as allegedly being obvious over AT in view RU, further in view of admitted prior art. Claim 21 was rejected as allegedly being obvious over AT in view of RU, further in view of Wegner.
6. In support of the alleged obviousness of claim 1 in the Amendment of September 8, 2009, and claim 1 in the Amendment of August 18, 2010, the Examiner states:

AT describes a cleaning and disinfection composition and a method using thereof comprises water, potassium permanganates and sodium peroxodisulfate (claimed second oxidizing agent, whose oxidation potential exceeds that of a mixture containing 50 mol% manganese VII and 50 mol% manganese VI and above that of H₂O₂- to OH-) (abs.; page 6, line 25-30). Unlike claimed invention, AT doesn't describe a pH buffer substance such as primary and/or secondary alkali carbonate. RU describes a disinfection composition that includes potassium permanganate and sodium carbonate (claimed primary alkali carbonate) (abs.). One skilled in the art would find it obvious to add sodium carbonate in light of RU because he teaches the solution having such compound can be used for disinfection and sterilization of different objects (abs). Therefore, using known elements with no changes in their respective functions, in this case using composition having sodium carbonate for the disinfections purposes, would be obvious and have yielded predictable results to one of ordinary skill in the art at the time of the invention was made. [See paragraph 2 in the Office Action of February 18, 2010 and paragraph 2 in the Office Action of November 2, 2010.]

In short, the Examiner's position is that it would have been obvious to add sodium carbonate to the composition of AT in light of RU to arrive at a composition (Composition 1 below) having water, potassium permanganates, sodium peroxodisulfate, and sodium carbonate, because RU teaches that the solution having sodium carbonate can be used for disinfection and sterilization of different objects.

7. This declaration under 37 CFR 1.132 is being submitted to show the unexpected results of the claimed composition of the present invention (Composition 2 below) versus the abovementioned composition based on AT and RU (Composition 1). In particular, the present declaration is to demonstrate that adding an alkali carbonate such as sodium carbonate to a liquid composition of AT would **NOT** produce a storage-stable liquid composition. On the other hand, a liquid composition according to the present application, e.g., the liquid composition according to claim 8 (Composition 2), is storage-stable even though it contains an alkali carbonate.
8. I have conducted the present study in order to demonstrate the major differences between (1) a composition according to AT with addition of sodium carbonate (based on RU) (referred to as Composition 1) and (2) a carbonate-buffered, neutral aqueous (liquid) concentrate (that has to be mixed with caustic prior to use) according to the present invention (which is a reference composition referred to as Composition 2).
9. Compositions 1 and 2 were formulated as follows:

Composition 1: The solid composition according to Claim 6 of AT and sodium carbonate were dissolved in water at 22.7% w/w and 1.89% w/w, respectively, so as to make the final concentration of sodium peroxodisulfate in the liquid concentrate (which was 3.5% w/w) to be comparable to that in Composition 2. Also, the permanganate concentration in Composition 1 was increased as compared to the solid composition of Claim 6 of AT by ten fold, i.e., to 0.1% w/w, in order to give comparable colour intensity / absorbance read-outs as that of Composition 2.

Composition 2: The liquid composition according to Claim 8 of the '665 publication using the preferable concentrations recited in Claim 8, which reads:

8. The cleaning, disinfection, and indicator agent according to claim 1, wherein it has the following composition:
3-5% sodium peroxodisulfate, preferably 4%
0.06-0.08% potassium permanganate, preferably 0.07%
5-7% sodium tripolyphosphate, preferably
6% 9-11% sodium hexametaphosphate, preferably 10%
2.0-3.0%, preferably 2.6%, of a mixture of sodium carbonate and sodium hydrogen carbonate, preferably in the ratio 3:1

In short, Composition 2 contained 4% sodium peroxodisulfate, 0.07% potassium permanganate, preferably 0.07%, 6% sodium tripolyphosphate, 10% sodium hexametaphosphate, and 2.6 % of a mixture of sodium carbonate and sodium hydrogen carbonate in the ratio 3:1, in water to form an aqueous solution.

10. The compositions of Compositions 1 and 2 in grams are shown in Table 1:

Table 1: Tested materials and compositions:

	Formula	Composition 1, grams	Composition 2, grams
Caustic Soda	NaOH	70,5	
Potassium Tripolyphosphate	K ₅ P ₃ O ₁₀	32,8	
Sodium Persulphate	Na ₂ S ₂ O ₈	18,2	20,7
Potassium Permanganate	KMnO ₄	0,12	0,4
Sodium Tripolyphosphate	Na ₅ P ₃ O ₁₀		31
Sodium Hexametaphosphate	(NaPO ₃) ₆		51,7
Sodium Carbonate	Na ₂ CO ₃	10,1	10,1
Sodium Hydrogencarbonate	NaHCO ₃	3,4	3,4
Water, deionized	H ₂ O	400	400

11. Compositions 1 and 2 were prepared as follows: Over a time-period of ca. 1 minute, the solids were added to 400ml of water (room temperature, 20°C = 68F) in portions

of ca. 5% of the total amount added and subsequently dissolved in a 1000 ml borosilicate-beaker equipped with a magnetic, PTFE-coated stirrer. The temperature reached and video-clips were recorded.

12. Compositions 1 and 2 were stored in the dark (loosely capped borosilicate bottles) for 4 weeks at 40°C = 104°F and were analyzed for storage stability. The methods of analysis were as follows:

- Temperature: FLUKE 189-III multimeter w/ FLUKE stainless-steel Type-K thermoelement.
- Absorption spectra (VIS): Microplate-reader TECAN infinite M200, 10mm optical path-length.
- Formulation / specific gravity: SARTORIUS BP121S analytical balance plus volumetric glass-ware from SCHOTT / DURAN.
- Peroxodisulphate analysis: GLP-validated volumetric (ferrous ion / permanganate) method using analytical-grade reagents from Sigma-Aldrich, visual detection of end-point. See attached validation procedure / report from ARC laboratories, Austria.
- Digital imaging: PANASONIC Lumix LX3 still/video camera, with cold-cathode backlit illumination.

13. The results of the storage stability tests on Compositions 1 and 2 are shown in Table 2:

Table 2: Results dissolution testing and storage stability Compositions 1 and 2:

Parameter	Composition 1	Composition 2	Unit
Time until full (or maximum degree of) dissolution	3	20	minutes
<i>Temperature reached during dissolution</i>	<i>71 / 160</i>	<i>32 / 90</i>	<i>°C / F</i>
<i>Dissolution complete with no residues</i>	<i>no (crystals visible)</i>	<i>yes</i>	
Colour after complete dilution	Violet / Blue	Purple	
Colour after 4 weeks of storage @ 40°C = 104F	Green (yellowish)	Purple	
Predominant manganese species after 4 weeks of storage @ 40°C = 104F	VI > II	VII	oxidation state Mn
Specific gravity @ 20°C / 68F	1.22	1.18	g/cm ³
Oxidiser content, calculated (theoretical value)	3.4	4.0	% w/w Na ₂ S ₂ O ₈
Oxidiser content, measured, after dissolution	1.5	4.3	% w/w Na ₂ S ₂ O ₈
Oxidiser content, measured, after 4 weeks @ 40°C / 104F in the dark	0.2	4.2	% w/w Na ₂ S ₂ O ₈

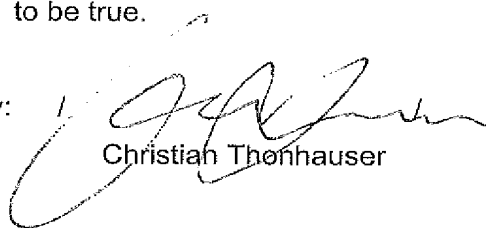
14. The conclusions based on the above results in Table 2 are the following:

- (a) Other than Composition 2, which maintained its purple color after 4 weeks of storage at 40°C = 104F, both Compositions 1 and 2 changed their colors from purple or violet to green. **This demonstrates that Composition 1 was NOT storage-stable at 40°C = 104F for even 4 weeks of storage, while Composition was storage-stable under identical conditions.**
- (b) During dissolution of the ingredients of Composition 1, the temperature reached 71°C / 160F versus 32°C / 90F for Composition 2. The higher temperature during dissolution of the ingredients of Composition 1 could have resulted in a substantial decomposition of the oxidizers of Composition 1.

(c) The dissolution of the ingredients of Composition 1 was not complete, resulting in visible crystals, versus the dissolution of the ingredients of Composition 2, resulting in no residues.

15. I hereby acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001) and may jeopardize the validity of the present application or any patent issuing thereon. All statements made of my own knowledge are true, and all statements made on information and belief are believed to be true.

By:



Christian Thonhauser

Date: November 18 2010